

## **REMARKS**

### **Status of the claims**

Claims 1-5 and 7-15 were pending in the subject application, of which claims 8-13 had been withdrawn from consideration by the Examiner. With this submission, claims 1, 4, 5 and 14 have been amended; claims 2 and 8-13 have been canceled without prejudice to future prosecution; and claims 16-18 have been newly added. Hence, upon entry of this paper, claims 1, 3-5, 7, and 15-18 will be pending in the subject application and under active consideration.

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **Claim amendments**

Claim 1 has been amended to incorporate the language of original claim 2 and can thus find support therefrom. New claim 16 is based on original claim 6. Support for new claim 17 may be found at least in paragraph 29 of the as-filed application; support for claim 18 may be found at least in paragraph 20 of the same disclosure. Hence, Applicant respectfully submits that no new matter has been introduced with these amendments.

### **Claim rejections under 35 U.S.C. § 102**

Claims 1-3, 5, 7 and 14 remain rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 6,004,582 to Faour *et al.* ("Faour"); claims 1, 2, 4, 5, 7, 14 and 15 remain rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. 6,197,331 to Lerner *et al.* ("Lerner"); and claims 1, 2, 5-7 and 14 remain rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. 3,065,143 to Christenson *et al.* ("Christenson"). Applicant respectfully traverses these rejections on the following grounds.

The claims, as amended, are directed to a sustained release pharmaceutical dosage form *consisting of*, in relevant part, (i) a sustained release matrix comprising a mixture of a pharmaceutically active agent and a polymeric material; and (ii) a *retaining means* for securing

the dosage form in a buccal or sublingual location. None of the cited references teach these elements.

Faour, for example, teaches osmotic compositions which require a semi-permeable membrane to achieve osmosis. *See, e.g.*, Abstract. The present claims, however, do not “consist of” such a membrane. Lerner discloses compositions wherein the “the minimal essential components” for the drug-containing layer include “at least one polymer, at least one pharmaceutical, and at least one plasticizer.” Col. 8, l. 35-38 and 50-53. However, the claimed invention does *not* “consist of” a plasticizer. Lastly, Christianson is silent on “a retaining means for securing the dosage form in a buccal or sublingual location” as required of the claimed invention.

Hence, insofar as an anticipatory reference must disclose each and every element of a claimed invention, Applicant respectfully submits that the cited references cannot defeat the novelty of the claimed invention. Hence, Applicant respectfully requests the withdrawal of subject rejections.

## **Conclusion**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37

C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to read "Sunit Talapatra", is written over a horizontal line.

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